

Declaration - FDA

VEGAFLEX 83



Document ID: 43113



VEGA

1 General information

FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of product-contacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR). Always use a suitable, FDA-approved process seal.

The USP (United States Pharmacopeia) is an official authority issuing the quality standards for drugs and medical products. USP checks and documents also food additives as well as materials and their effect on living tissue.

Regulation (EC) No. 1935/2004 of 27/10/2004 aims at securing a protective level for human health and the consumer of objects and materials coming into contact with foodstuffs. The main focus of the regulation is ensuring that good manufacturing practices are maintained. For us, the first aspect of good manufacturing means realizing the goal of ensuring that components potentially coming into contact with foodstuffs are designed so that under foreseeable conditions a migration of constituent substances is largely avoided or does not occur in quantities that endanger human health or cause unacceptable changes in the composition or organoleptic properties of the material. We fulfill these general requirements by purchasing components delivered with proof of compliance with FDA requirements and, when it comes to materials not subject to explicit FDA requirements, by obtaining a "No Objection Letter" from the Public Health Service of the Food and Drug Administration as well as requesting the expert opinion of independent (accredited) laboratories and organizations.

Under the second aspect of good manufacturing practice we understand ensuring the traceability of components and products potentially coming into contact with foodstuffs throughout all stages of manufacturing and sales. This is guaranteed by our quality management system according to ISO 9001 und ISO 14001.

2 Manufacturer declaration

We hereby declare that the materials of the product-contacting parts of the following versions of VEGAFLEX 83 meet the requirements of the Food and Drug Administration.

Furthermore, the wetted plastics and elastomers of the following versions of VEGAFLEX 83 meet in their composition the requirements according to USP Class VI. For the following versions of VEGAFLEX 83 the goals of directive (EC) No. 1935/2004 of 27.10.2004 are fulfilled.

Versions

Listing VEGAFLEX 83 foodstuffs		
FX83.*B*****	FX83.*E*****	FX83.*F*****
FX83.*H*****	FX83.*G*****	FX83.*I*****

This declaration is based on the following certificates:

- The official statement of the Public Health Service of the Food and Drug Administration on the implemented stainless steels (College Park, MD 20740 of 22.11.2004)
- The official statement of the supplier of the isolating sleeve of PEEK LSG and the O-rings of FKM, FFKM, PPE and EPDM on conformity with FDA as well as USP Class VI regulations.

Furthermore, it is the responsibility of the operator to ensure compliance with any additional food and process-specific requirements.

Note: This declaration is valid for instruments on which the document number "43113" is explicitly shown on the type label or the accompanying documentation.

Printing date:

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All statements concerning scope of delivery, application, practical use and operating conditions of the sensors and processing systems correspond to the information available at the time of printing.

Subject to change without prior notice

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